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10/078,042

02/19/2002

Donald C. Roe

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05/19/2008

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EXAMINER

KOPPIKAR, VIVEK D

ART UNIT

PAPER NUMBER

3626

MAIL DATE

DELIVERY MODE

05/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/078,042

Applicant(s)

ROE ET AL.

Examiner

VIVEK D. KOPPIKAR

Art Unit

3626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of the Application

1. Claims 1-10 and 14-20 have been examined in this application. This communication is a non-final office action in response to the Request for Continued Examination (RCE) filed on February 5, 2008.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 5, 9-10 and 14-20 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,319,199 to Sheehan in view of US Patent Number 6,055,506 to Frasca, Jr. and in even further view of US Patent Number 5,828,751 to Walker.

(A) As per claim 1, a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

- a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);
- b) a data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);
- d) an information presentation mechanism displaying the information pertaining to the health of an individual (Sheehan: Col. 4, Ln. 54-67).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating information pertaining to the health of an individual wherein the data analysis mechanism performs at least one analysis selected from the group of statistical control chart techniques based on the historical or recent health data of the individual, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Frasca, Jr.: Col. 13, Ln. 58-Col. 14, Ln. 6). (Note: In the cited portion of Frasca, Jr. attribute data analysis is taught and the attribute is a patient's temperature). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

Sheehan in view of Frasca, Jr. do not explicitly teach that the data acquisition mechanism and the data measurement mechanism are disposed on a single handheld device, however, this feature is well known in the art as illustrated by Walker (Col. 10, Ln. 47-55). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. with the aforementioned teachings from Walker with the motivation of providing a means of handheld data measurement and certification as recited in Walker (Col. 10, Ln. 47-55).

(B) As per claim 2, in the system of Sheehan in view of Frasca, Jr. the at least one data analysis mechanism further comprises data analysis software (Sheehan: Col. 2, Ln. 58-62 and Col. 7, Ln. 47-59).

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(C) As per claim 5, in the system of Sheehan in view of Frasca, Jr. the at least one data measurement mechanism includes a sensor (Sheehan: Col. 1, Ln. 29-38).

(D) As per claim 9, Sheehan in view of Frasca, Jr. in view of Walker teach a method for improving the health of an individual (Sheehan: Abstract) including the steps of:

- a) selecting at least one health parameter appropriate for the particular individual based on the individual's medical condition and medical history, current or recent health event(s) of interest, age and/or demographics, or any other health parameter of interest to the individual, caregiver, or medical professional (Sheehan: Col. 4, Ln. 12-18);
- b) measuring the at least one health parameter of interest and pertinent environmental or qualitative information to produce data (Sheehan: Col. 2, Ln. 23-46);
- c) acquiring the data for storage and subsequent analysis (Sheehan: Col. 2, Ln. 23-46);
- and
- e) presenting the information (alert) to the individual, caregiver, or medical professional (Sheehan: Col. 6, Ln. 47-59 and Col. 7, Ln. 13-19).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

- d) analyzing the data via at least one data analysis mechanism to define at least one of an out-of-control situation requiring intervention and/or potential causes or remedies of an out-of-control situation wherein the data analysis mechanism performs at least one analysis selected from the group of statistical control chart techniques based on the historical or recent health data of the individual, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca

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with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

(E) As per claims 14-20, these claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr. in view of Walker, as applied to Claim 9, and in even further view of Official Notice.

As per claims 14-20, the Office takes the position that the recited steps are steps which are well known in the art for analyzing data using statistics and therefore the Office takes Official Notice with regard to these features. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Walker with these steps with the motivation of having a systematic means of analyzing the data and determining outliers in the data set so that the patients (individuals) who represented these outliers could be alerted of their potentially out-of-control situation (e.g. health condition).

(F) As per claim 10, in the method of Sheehan the information presented is selected from the group: statistical analysis, out-of-control points, control rules violations, specification violations, medical limit violations, medical condition related information, advertising for products related to the individual's medical condition or health event, help guides, summary screens (Sheehan: Figures 3 and 5 (220); Col. 4, Ln. 62-68 and Col. 7, Ln. 4-18).

4. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr. in view of Walker and in even further view of US Patent Number 6,658,287 to Litt.

(A) As per claim 6, Sheehan in view of Frasca, Jr. in view of Walker in view of Litt teaches a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

- a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);
- b) at least one data acquisition mechanism transferring the data from the data measurement mechanism to a storage medium wherein the at least one data acquisition mechanism is selected from the group: a tablet PC, voice recognition, and telemetry based systems (Sheehan: Col. 2, Ln. 34-46 and Col. 8, Ln. 18-32);
- d) an information presentation mechanism displaying the information pertaining to the health of an individual (Sheehan: Figures 3 and 5 (220) and Col. 4, Ln. 54-67);

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

- c) at least one data analysis mechanism generating information pertaining to the health of an individual (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

Sheehan in view of Frasca, Jr. do not explicitly teach a handheld data measurement mechanism, however, this feature is well known in the art as illustrated by Walker (Col. 10, Ln. 47-55). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. with the aforementioned teachings from Walker with the motivation of

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providing a means of handheld data measurement and certification as recited in Walker (Col. 10, Ln. 47-55).

Sheehan in view of Frasca, Jr. in view of Walker do not teach or suggest that the displayed information comprises a statistical control chart based on the historical or recent health data of the individual, however, this feature is well known in the art as illustrated by Litt (Col. 13, Ln. 18-41). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Walker with the aforementioned teachings from Litt with the motivation of having a means of making predictions, as recited in Litt (Col. 1, Ln. 10-18).

(B) As per claim 7, in the system of Sheehan in view of Frasca, Jr. at least one data acquisition mechanism includes a handheld device selected from the group: a PDA and a handheld PC (Sheehan: Figures 3-5 and Col. 8, Ln. 18-32).

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca in view of Walker and in further view of US Patent Number 5,464, 102 to Falcone and in even further view of US Patent Number 6,540,674 to Zadrozny.

(A) As per claim 8, the system of Sheehan in view of Frasca, Jr. includes:

a) a data measurement mechanism generating data relevant to a particular health condition of the individual (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) at least one data acquisition mechanism transferring the data from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);

d) an information presentation mechanism displaying to the individual the information pertaining to the health of an individual, wherein the at least one information

presentation mechanism is selected from the group: a graphical summary screen, an icon based summary screen, a help guide, an anthropomorphic help guide, and synthesized speech (Sheehan: Figures 3-5; Col. 4, 54-67 and Col. 6, Ln. 47-59).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating insights relevant to a particular health condition (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

Sheehan in view of Frasca, Jr. do not teach that the data acquisition mechanism is adapted to perform a preliminary analysis on the data and provide an output (e.g. an alarm) when the data comprises a value that is outside of a target, however, this feature is taught by Falcone (Col. 2, Ln. 9-18 and Col. 4, Ln. 22-25). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca with the aforementioned teachings from Falcone with the motivation of having a detection means whenever a patient's state was altered, as recited in Falcone (Col. 1, Ln. 5-10).

Sheehan in view of Frasca, Jr. in view of Falcone do not teach that the information includes at least one level of intervention (i.e. recommendation) when the data comprises a value that is outside of a control limit, however, this feature is taught by Zadrozny (Col. 2, Ln. 33-38 and Col. 10, Ln. 28-32). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the

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combined teachings of Sheehan in view of Frasca, Jr. in view of Falcone with the aforementioned teachings from Zadrozny with the motivation of having a means of recognizing events which pose a danger to ill persons and providing assistance to these ill persons, as recited in Zadrozny (Col. 2, Ln. 4-9).

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr. in view of Walker, as applied to Claim 1, above, and in further view of US Patent Number 5,920,478 to Ekblad.

(A) As per claim 3, Sheehan does not teach that the at least one data analysis mechanism further comprises automatic or triggered recalculation of control limits based on top demonstrated historical performance, however, this feature is taught by Ekblad (Col. 11, Ln. 52-59). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Ekblad with the motivation of having a means of allowing adaptive updating in response to changes (variations) in data, as recited in Ekblad (Col. 11, Ln. 52-59). In the alternative, the examiner takes Official Notice that this feature is well known in the art and at the time of the invention one of ordinary skill in the art would have been motivated to have modified the system of Sheehan with this aforementioned feature with the motivation of having a means to set the control limits so that they reflected and were up to date to changes in the raw historical performance data that was obtained from various patients.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr. in view of Walker, as applied to Claim 1, above, and in further view of US Patent Number 6,642,592 to Loman.

(A) As per claim 4, Sheehan does not teach that the reliability engineering analysis includes time between failures and failure duration, however, this feature is taught by Loman (Col. 5, Ln. 14-16). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Loman with the motivation of having a fault resolution means (Loman: Col. 10-14) to detect faults and failures within the system of Sheehan.

Response to Arguments

8. Applicant's arguments filed on February 5, 2008 have been fully considered but they are not persuasive. The applicant's arguments will be addressed in the same order as they were addressed in the "Remarks" filed on February 5, 2008.

(1) Applicants argue, with regards to Claim 1, that Frasca Jr. does not state that the predetermined limit is generated based on the patient's own data. However, the Office would like to point out that Claim 1 does not have a limitation stating that the predetermined limit is generated based on the outpatient's own data.

(2) Applicants argue, with regard to Claims 1 and 9, that they are unable to find any teaching or suggestion in Sheehan or Frasca of a data analysis mechanism performing statistical control chart techniques based on the historical or recent health data of the individual. However, the Office would like to point out that applicants have claimed this limitation in a Markush group form and the prior art (Frasca, Jr.) teaches one of the other items in the Markush group, mainly, attribute data analysis (Frasca, Jr.: Col. 13, Ln. 58-Col. 14, Ln. 6).

(3) Applicants argue, with regards to Claims 1 and 7, applicants state that the prior art of record does not teach or suggest a data acquisition mechanism and a data measurement

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mechanism both disposed on a single handheld device. However, this argument is moot over the new ground of rejection over the Walker reference.

(4) Applicants argue, with regards to Claim 6 that the prior art of record does not teach or suggest that information is displayed on a statistical control chart based on historical or recent health data of the individual. However, this argument is moot over the new ground of rejection over the Litt reference.

(5) Applicants argue, with regards to Claim 9, that the Sheehan reference does not teach or suggest measuring environmental or qualitative data. However, Sheehan does in fact teach this very feature of collecting data relating to a patient's eardrum which the Office interprets as constituting both environmental data (i.e. the environment in the patient's eardrum) and qualitative data (i.e. the quality of the patient's eardrum) (Sheehan: Col. 1., Ln. 6-14 and Col. 4, Ln. 37-45).

(6) Applicants argue, with regards to Claim 9, that Frasca does not suggest analyzing data to define an out-of-control situation wherein the term out-of-control is defined to mean a statistical control rule which is intended to indicate a statistically significant change in a parameter of interest for an individual as opposed to normal variation within the statistically likely boundaries for the individual. However, the Office would like to note that nowhere in Claim 9 is the term out-of-control situation defined, and therefore this term is given its plain and ordinary meaning. In this case, the Office has interpreted the term out-of-control to mean any data point which is outside of a control limit or target or normal range.

(7) Applicants argue that the target limits of Falcone are not the same as the control limits recited in the present applicant because the dynamic limits of Falcone are merely

target limits that are modified according to an expected reaction of a patient's health parameter in response to a procedure and which are programmed to return to the original target limits over time. However, the applicants have not given a precise explanation or definition as to what they regard to be a target as recited in Claim 8. Therefore, the term target is given its plain and ordinary meaning and as a result the Office takes the position that the target limit in Falcone is the same as the target that is required by Claim 8.

(8) Applicants argue that the Falcone reference does not teach a preliminary analysis because the data is analyzed only once. However, the applicants do not point that portion of Falcone that states this. The Office takes the position that Falcone in fact does teach the feature of a preliminary analysis as is set forth in the rejection of Claim 8 above and also set forth in Falcone (Col. 2, Ln. 9-18 and Col. 4, Ln. 22-25).

(9) Applicants argue that, with regards to Claim 8, that the Sheehan, Frasca, and Zadrozny references are non-analogous art. The Office takes the position it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all the references used are relevant because they all relate to and address the particular problem of improving the process of acquiring and measuring a patient's data.

(10) Applicants argue that, with regards to Claim 8, that the Zadrozny reference does not teach at least one level of intervention when the data comprises a value that is outside of a control limit. However, as set forth above in the rejection of Claim 8, Zadrozny does in fact teach this very feature (Zadrozny: Col. 10, Ln. 28-32).

Conclusion

9. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vivek D Koppikar/
Primary Examiner, Art Unit 3626